

Policy

*For further details of how to complete this template please refer to the Policy / Document Guide on the last page*

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| Reference: | Clini 103 |
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Please indicate what type of document this is (please check):

☒ Policy

☐ Procedure

☐ Guideline

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| Description: Description: Description: cid:image004.png@01D63808.FFA11950 | |
|  | Policy on a Page  **CLINI 103 - Patient Safety Incident Response Framework (PSIRF) Policy** |
| Policies can sometimes be hard to digest, but all colleagues need to be aware of their key points.  The key points from this policy are on this page. | |
|  | What Does the Policy Cover?  This policy covers Spire Healthcare’s patient safety incident reporting and incident response processes.  Non-clinical incidents are covered in policy (TBC) |
|  | Who are the key groups who need to be aware of this policy (please check)?  ☒ Hospital clinical colleagues  ☒ Consultants  ☒ Non-clinical colleagues  ☒ Everyone  ☒ Other (please specify) - Coroners, ICB's, Regulators |
|  | What Does It Say?   * This policy outlines the organisations PSIRF strategy, patient safety incident reporting processes and responses. |
|  | What Do I Need to Do?   * Colleagues need to familiarise themselves with a general understanding of the patient safety incident response process and the role that they play in this. |
|  | Further Information   * The full policy can be found on the intranet * Speak to your governance lead * Deputy Director of Integrated Quality Governance |
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# PURPOSE

## This policy supports the requirements of the [Patient Safety Incident Response Framework (PSIRF)](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-1.-PSIRF-v1-FINAL.pdf) and sets out Spire Healthcare’s approach to responding to patient safety incidents (PSIs) for the purpose of learning and improving patient safety.

## NHS England (2022) defined patient safety incidents as:

## ***‘…. unintended or unexpected events (including omissions) in healthcare that could, or did, harm one or more patients’.***

## PSIRF supports organisations to respond to incidents in a way that maximises learning and improvement and advocates a co-ordinated and data-driven response. It embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

## 

## This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of PSIRF:

## This policy should be read in conjunction with our current patient safety incident response plan (Appendix 1). The PSIRF plan details the organisation’s patient safety priorities for the year.

## Spire Healthcare has committed to ensuring that we fully embed the PSIRF and meet its requirements. We have therefore used the NHS England patient safety response standards (2022) to frame the resources and training required for all our colleagues including specific training for those involved in patient safety incidents.

# SCOPE

## This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all of Spire Healthcare’s clinical services including:

## 39 hospitals (England (35), Scotland (2) and Wales (2)) delivering all, or a selection of, the following:

## planned surgery to adults.

## planned surgery to children and young people.

## cancer services

## diagnostic services (e.g., imaging or pathology)

## decontamination (sterilisation) services

## critical care (for example, intensive care, following surgical or medical procedures).

## Spire Clinics

## Primary Care services

## Vita

## This policy relates to responses to patient safety incidents that are solely for the purpose of learning and improvement. Any response that seeks to find liability, accountability or causality is beyond the scope of this policy (see below at 2.3).

## Other processes, such as those shown below differ from those of a patient safety incident response and are not included in this policy:

* Legal Claims (FIN14)
* Coroners’ investigations
* Police investigations
* Human Resources investigations (HR15)
* Complaints (HOP02)
* Financial investigations (FIN 24)
* Medical Professional Standards investigations (MED06)
* Safeguarding concerns (Clini10)
* Non-Patient Safety incident responses (Policy no. TBC)
  + Health and Safety
  + IT (including information governance)
  + Estates and facilities issues

## Information from a patient safety response process can be shared with those leading other types of responses, but other processes should not influence the remit of a patient safety incident response.

## PSIRF does not look for who is to blame or at fault, it forms part of our commitment to developing a just and learning culture, building openness and transparency, ensuring everyone is treated fairly and that we learn from any errors.

## PSIRF Policy will see Spire Healthcare move away from the Serious Incident Framework (SIF) to a new approach to incident management, one which enables examination of a wider range of patient safety incidents “in the spirit of reflection and learning” rather than as part of a “framework of accountability”.

## 

## The PSIRF policy gives us the opportunity to promote a system-based approach (principally systems engineering initiative for patient safety, SIEPS) to learn from incidents and events. By using a systems approach will help to remove a focus on individuals and human error when investigating incidents.

# OUR PATIENT SAFETY CULTURE

## At Spire Healthcare, our purpose is to “make a positive difference to people’s lives through outstanding personalised care”. A culture of safety is fostered throughout the organisation, with a one of our key strategic pillars being to build on quality. We reflect our commitment in our values: driving clinical excellence, We recognize that a strong patient safety culture is essential to providing high-quality care and preventing adverse events.

## In Spire Healthcare, PSIRF will enable us to establish and further embed the management of patient safety incidents within our learning and improvement agenda. Within PSIRF it is important that those impacted (colleagues, Consultant partners, patients/family) by a patient safety incident are involved as soon as possible to ensure that as much learning is taken from the incident as possible. This timely collaboration in working with all those involved will ensure that the organisation continues to grow its patient safety culture.

## The focus of patient safety incident responses will be for the purpose of learning and improving our safety for the benefit of patient’s, colleagues and consultant partners.

## Spire Healthcare’s safety culture can be defined under the following categories:

## **Leadership Commitment**

## Our leadership team is dedicated to patient safety.

## They lead by example, emphasizing the importance of safety in all aspects of our operations.

## They provide the necessary resources and support to ensure that patient safety initiatives are successful.

## **Open Communication**

## We encourage open and transparent communication at all levels of the organisation with initiatives including:

## Freedom to speak up guardians and ambassadors.

## Surgical safety guardians.

## Colleagues and consultant partners are encouraged to speak up about safety concerns, near-miss incidents, or adverse events. We believe that every voice matters in ensuring patient safety.

## **Reporting and Learning**

## Our PSIRF policy plays a central role in our patient safety culture and developing a just culture across Spire Healthcare.

## It provides a structured framework for reporting and documenting incidents, near-misses, and unsafe conditions.

## We use these reports as opportunities for continuous learning and improvement.

## **Training and Education**

## We provide ongoing training and education to our colleagues on patient safety principles, best practices, and the use of the PSIRF system as detailed within the PSIRF training needs analysis (TNA) and associated training materials.

## The training programme will be designed to ensure that colleagues are confident in PSIRF processes. Participation data will be monitored to evidence our compliance.

## This will empower our employees to actively contribute to patient safety efforts.

## **Continuous Improvement**

## Patient safety is a dynamic and evolving field.

## We are committed to continuous improvement in our patient safety practices and ongoing training, reinforced with a strong QI Strategy and Framework which is supported by a programme of education, training and learning.

## Regular reviews of incident data, analysis of trends, and the implementation of evidence-based solutions are essential components of our approach.

## **Patient Involvement**

## We actively involve patients and their families in our safety efforts. Their perspectives and insights are invaluable in identifying potential risks and improving the patient experience, reinforced with a strong patient experience and patient engagement framework.

## **Safety is a priority.**

## Patient safety deeply embedded in our organisational culture.

## Safety principles guides our decision-making, policies, and procedures, ensuring that the well-being of our patients remains at the forefront of all we do.

## By promoting a patient safety culture characterized by leadership commitment, open communication, reporting and learning, training and education, accountability, continuous improvement, patient involvement, and safety as a core value, Spire Healthcare aims to provide the highest standard of care while minimising the risk of adverse events.

## **Just Culture**

## Just Culture is a principle that promotes a blame-free environment where people feel comfortable reporting errors and near misses without fear of reprisal. It is based on the understanding that accidents and incidents are often the result of multiple factors, including human error, system failures, and organisational culture.

## Spire Healthcare recognises the importance of ensuring that Just Culture is at the very foundation of all we do and supports a culture of fairness, openness and learning by making colleagues and consultant partners feel confident to speak up when things go wrong, rather than fearing blame. Supporting colleagues and consultant partners to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated.

## Appendix 27 Spire Healthcare Just Culture Managers step by step guide.

## **Psychological safety**

## Psychological safety is created in an environment where there is openness and trust that allows team members to feel comfortable taking risks and making mistakes. To be able to work in a psychologically safe environment, it is vital for healthcare professionals and patients to feel comfortable in sharing their concerns, fears or any other issues that might hinder (reduce) the quality of patient care.’ (Psychological Safety Academy, 2022).

# PATIENT SAFETY PARTNERS

## The Patient Safety Partner (PSP) is a new and evolving role developed by NHS England / Improvement to help improve patient safety. The main purpose of the role is to be a voice for the patients and community who utilise our services and ensure that patient safety is at the forefront of all that we do.

## It is recognised that the role of the Patient Safety Partner is a new role in both the NHS and the independent sector. Spire Healthcare has worked with NHS England and IHPN to define how this role will function within the independent sector. Clear guidance for the independent sector is yet to be confirmed however we are exploring this opportunity to fully understand how our patient safety partners will integrate within our services. Spire Healthcare will ensure that this new role compliments the patient engagement and experience framework to enable us to further add to the opportunity to hear our patients in patient safety event.

## During recruitment of PSPs consideration will be given to diversity and where gaps in partners with specific characteristics are identified, active recruitment will be led to ensure diversity in this key stakeholder group.

## It is envisaged that the Patient Safety Partners roles will be developed further during 2024.

# ADDRESSING HEALTH INEQUALITIES

## Addressing health inequalities is an organisational priority as seen through our purpose, ‘making a positive difference to people’s lives, through outstanding personalised care’. This will include but not be limited to the implementation of the PSIRF.

## Learning identified through patient safety incident investigations will ensure effective communication with all patients including those who have additional requirements due to physical or learning disabilities. Patient safety responses will continue to support health equalities through a variety of routes including quality improvement, lessons learned forums, systems, and process.

## Datix will allow for the details of patients to be directly drawn from associated patient administration and electronic health record systems, and Incident/Events can then be analysed by the nine protected characteristics (of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation) to give insight into any apparent inequalities.

## Spire Healthcare will directly address, as part of our response, any features of an incident which indicate that health inequalities may have contributed to harm or demonstrate a risk to a particular population group. This will include a tailored approach to different protected characteristics and appropriate adjustments made if required. When constructing our safety actions in response to any incident we will consider inequalities, and this will be inbuilt into our documentation and governance processes.

## Engagement of patients, families, colleagues, and Consultant partners following a patient safety incident is critical to the review of patient safety incidents and their response. Spire Healthcare is committed to ensuring our colleagues have appropriate training (e.g. Oliver McGowan and National Autistic Society) to ensure reasonable adjustments are made and that available tools such as easy read, translation and interpretation services and other methods as appropriate to meet the needs of those concerned and maximise their potential to be involved in our patient safety incident responses.

# ENGAGING AND INVOLVING PATIENTS, FAMILIES, COLLEAGUES and CONSULTANT PARTNERS FOLLOWING A PATIENT SAFETY INCIDENT

## PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, families, colleagues, and consultant partners). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required. Information leaflets are being developed for colleagues, patients and families involved in the incident.

## Spire Healthcare is committed to creating a culture of openness with patients, families, and carers particularly when clinical outcomes are not as expected or planned. There is a responsibility as well as a statutory requirement under CQC Regulation 20, Duty of Candour for all healthcare organisations to be open and transparent with patients and their families when things go wrong with treatment or care delivery. Registered professionals should also refer to their professional guidance with reference to Duty of Candour requirements. This forms the basic principle of our policy. For more information see FIN05 Duty of Candour policy.

## Patients and their families will be given the opportunity to ask questions and express their concerns. They will be kept informed of the progress of the incident response and the results of any recommendations. Additionally, they will be invited to participate in efforts to improve patient safety.

## For all patient safety incident investigations (or other learning responses where applicable), a patient engagement lead will be identified who will be responsible for initial contact with either the patient and/or their family/carer. The patient engagement lead will ensure the patient and/or their family/carer is kept informed of the progress with investigation timelines and ensure that any concerns identified are addressed. For all engagement with patients and/or their family/carer Spire Healthcare will adopt the NHS England four steps of engagement, of which training has been provided.

## A screenshot of a computer Description automatically generated

## Colleagues and Consultant partners impacted by a patient safety incident will be supported by the hospital and central management teams and in line with our Just Culture and psychological safety processes. In addition to this Spire Healthcare offers a colleague support service which can be utilised by all colleagues. Support is available 24/7 365 days a year which includes professional counselling.

# PATIENT SAFETY INCIDENT RESPONSE PLANNING

## PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond nationally set requirements, organisations can explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

## As per the ethos of PSIRF, Spire Healthcare will ensure that we take a proportionate approach in our incident responses to solidify our commitment to improving our services for patients.

## Our PSIRF planning has quality improvement central and front of mind throughout its development. As a result, there is a direct correlation between our PSIRF plan and our quality improvement agenda. It is our firm intention to maintain and build on this link.

## Additionally, we will continue to review safety activity information from a range of sources to ensure that we are focusing on appropriate areas (Appendix 1). This will continue the work that went into establishing our patient safety profile and plan.

## National (as defined by the NHS) and group (Spire) priorities are contained within the PSIRF Plan and will be updated annually. These priorities will have a clearly defined incident response type including:

* Patient Safety Incident Investigation – NHS England
* [Swarm huddle](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Swarm-huddle-v1-FINAL.pdf)- NHS England
* After action Review – NHS England
* [Round table](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-MDT-review-v1_FINAL.pdf) (MDT Meeting in NHS England PSIRF Framework) (and within Spire Health care is used in our Key Safety Indicator Reviews)

# RESOURCES AND TRAINING TO SUPPORT PATIENT SAFETY INCIDENT RESPONSE

## Spire Healthcare have undertaken an extensive training programme to ensure that our colleagues are fully trained ahead of the implementation of PSIRF. This training programme was designed using the NHS England patient safety response standards which details the training and competencies colleagues require when undertaking patient safety incident responses under PSIRF.

## The organisation designed its training programme to fully comply with NHS England guidance with the following sessions delivered throughout 2023:

## Systems Approach to learning from patient safety incidents (2 days)

## Oversight of Learning (1 day)

## Patient Engagement (1 day)

## Senior Management Team (SMT) Awareness Sessions (2 hours)

## The training sessions were delivered by an approved NHS England PSIRF training company (Facere Melius). Great efforts were made to ensure that the training was bespoke to Spire Healthcare. It was very important to make sure that the training recognised that PSIRF in the independent sector was different to the acute NHS sector. The training recognised these differences and was adjusted to maintain its effectiveness.

## Spire Healthcare has developed a training programme for 2024 to further develop and support the implementation of PSIRF across the Group. The training will maintain the required levels of competency for existing colleagues and development for new colleagues.

# PATIENT SAFETY INCIDENT RESPONSE PLAN

## Our plan sets out how Spire Healthcare intends to respond to patient safety incidents over a period of 12 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected, as well as the plan.

## National (as defined by the NHS) and group (Spire) priorities are contained within the PSIRF Plan and will be updated annually. These priorities will have a clearly defined incident response type including:

* Patient Safety Incident Investigation – NHS England
* [Swarm huddle](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Swarm-huddle-v1-FINAL.pdf)- NHS England
* After action Review – NHS England
* [Round table](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-MDT-review-v1_FINAL.pdf) (MDT Meeting in NHS England PSIRF Framework) (and within Spire Health care is used in our Key Safety Indicator Reviews)

## Spire Healthcare’s PSIRF plan (Appendix 1) describes how the plan was developed including:

# Engagement with key stakeholders internally and externally

# Profiling by analysing historic patient safety incidents, Business Intelligence analytics, complaints, claims, colleague feedback and risk assessments.

# Reviewing the Quality Improvement (QI) Framework and projects for 2023

# Agreeing the Spire Healthcare Group (local) priorities

# Agreeing the patient safety incident response methods

# REVIEWING OUR PATIENT SAFETY INCIDENT RESPONSE POLICY AND PLAN

## Our patient safety incident response plan is a ‘living document’ that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the plan every 12 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 months.

## Updated plans will be published on our website, replacing the previous version.

# RESPONDING TO PATIENT SAFETY INCIDENTS

## **Patient safety incident reporting arrangements**

## The purpose of incident reporting is to deal with the issues that cause incidents and accidents, not to blame individual people. This does not detract from individuals’ responsibilities to carry out their duties in an appropriate and professional manner, or from Spire Healthcare’s right to carry out disciplinary measures where required, such as cases involving gross professional misconduct or repeated failings.

## Incident reporting is currently the responsibility of all colleagues and is done so via the organisation’s incident reporting system; Datix. Over 2024 the organisation will move to DCIQ, which will allow us to record incidents, investigations and participate in the NHS England ‘Learn from Patient Safety Events’ (LFPSE) service, which will improve how it learns from patient safety events for NHS England commissioned patients.

## Department managers are responsible for ensuring that colleagues are supported when reporting incidents and escalating to the senior management team at the hospital where appropriate.

## The Hospital Director (or equivalent for clinics and some GP services) is responsible for ensuring suitable committee arrangements are in place to review incidents, complaints and claims in line with Spire Standards for Hospital Governance CLIN 01.

## The Group have an agreed process for determining the initial level of incident response (Patient Safety Incident Response Flowchart, Appendix 18), this will be undertaken at the weekly rapid response meeting.

## For all incidents, the Hospital Director or Director of Clinical Services (or an individual appropriately designated to do so) is responsible for confirming that any action which is deemed necessary in immediate response to the incident (particularly to secure the safety of patients, colleagues and consultant partners and others) has been completed.

## **Initial levels of patient safety incident response**

## **Datix (No enhanced investigation required)**

## The focus on learning should be maintained with any key learnings actioned and shared.

## The incident will be closed and will be included in analysis of trends quarterly.

## **Patient Safety Incident Review (PSIR)**

## Where an incident immediately meets the criteria for a Patient Safety Incidents Investigation (PSII - as detailed in the PSIRF Plan and Appendix 28). PSIR form will be completed within 2 working days and sent for review to the Patient Safety Incident Response Group (PSIRG) via [$HospSeriousAdverseEventNotification@spirehealthcare.com](mailto:$HospSeriousAdverseEventNotification@spirehealthcare.com)

## **Case review (e.g. Blood transfusion, VTE, IPC, Pressure Ulcer)**

## A case review will be carried out by the hospital clinical team, to determine whether there were any safety issues, learning and improvement opportunities.

## Blood transfusion and laboratory medicine incident investigation (Appendix 14)

## VTE Case Review (Appendix 15)

## Pressure Ulcer Case Review (Appendix 16)

## SSI Case Review (Appendix 17)

## **KSI Review (Appendix 13)**

## The Key Safety Indicators (KSI) process uses the round table or MDT meeting methodology and will involve a review of the following incident types:

## Unplanned Readmission

## Unplanned Return to Theatre

## Unplanned Transfer Out (which will also include unplanned internal transfer to ITU for our Level 3 sites)

## The hospital will hold a regular (at least monthly­) KSI meeting (attended by key leads) which will look at each of the incidents reported focussing on the key aspects of the patient’s journey as detailed in the KSI TOR (Appendix 10).

## Following the round table review the incident can be concluded as avoidable or unavoidable.

## **Case Review / KSI Review – Unavoidable incident**

## Following the initial review, where an incident is deemed unavoidable the rationale for this should be documented within Datix and where appropriate the actual harm caused downgraded. The outcome of any review must be recorded on the appropriate template and attached to Datix. For unavoidable incidents, the focus on learning should be maintained with any key learnings actioned and shared.

## The incident will be closed and will be included in analysis of trends quarterly.

## **Case Review / KSI Review – Avoidable incident**

## Following the initial review, where an incident is deemed avoidable, the outcome must be recorded on the appropriate template and escalated to the Patient Safety Incident Review Group (PSIRG) and further investigation will be determined and undertaken.

## **Patient safety incident response**

## **PSIIs (as defined in Plan)**

## Following a reported PSII, the Hospital Director/ Unit Manager or Director of Clinical Services will appoint a colleague to undertake the incident response within 60 working days.

## **All avoidable Incidents (including near misses) falling below the threshold of a PSII**

## All avoidable incidents will require an incident response by an appropriately trained colleague to ensure that any learning from the event and subsequent actions are completed. The methods of incident responses can include those detailed in Spire Healthcare’s PSIRF Plan and are listed as follows:

* Swarm huddle.
* After Action Review
* Round table (MDT Meeting in NHS England PSIRF Framework)

## **Trend analysis and Thematic Reviews**

## All incidents logged on to Datix will be regularly analysed for trends and considered for thematic reviews.

## A trend reporting programme will be developed, and a focussed learning report will be produced based on the thematic reviews and will be presented to the Safety, Quality and Risk Committee (SQR).

## **Monitoring and Reporting**

## The national Patient Safety Incident Response Group (PSIRG) members are assigned to review and approve every reported Patient Safety Incident Investigation (PSII) submitted by hospitals within 5 working days. The PSIRG recommends national actions, such as changes to policy, training, or care pathways, arising from individual incidents or trends, and these are reported to SQR.

## The Spire Healthcare Executive Committee receives weekly reports of PSII and other enhanced patient safety incident responses which are also monitored by the Safety, Quality and Risk Committee and the Clinical Governance and Safety Committee.

## Incident data will be reviewed regularly (weekly) within the National Integrated Quality Governance Team to ensure data integrity, quality (including quality of actions), and compliance with timeframes. This structured approach to incident data monitoring will make sure that the reported incident data is correctly represented on the incident reporting system. As part of the data validation process assistance and guidance will be provided to individual hospital sites (where required) to improve incident data quality.

## The National Integrated Quality Governance Team will ensure regular monitoring of this policy and escalate any episodes of non-compliance with Spire Healthcare’s incident reporting standards through the ward to board accountability and assurance model.

## 

## **Responding to cross-system incidents/issues**

## Spire Healthcare hospitals which provide care to NHS patients must agree with their local NHS organisations how they will report and investigate patient safety incidents which affect a patient that has received care in both places. For example, where a patient has their surgery in a Spire Healthcare Hospital but is then moved into the NHS for another part of their care.

## Where parts of a patients care pathway is provided in any other provider, including the independent sector, *this must also be considered.*

## Collaboration with the relevant ICB should be undertaken to ensure cross system incident investigation and shared learning.

## ***N.B. How this is done must be agreed in writing.***

## **Timeframes for learning responses**

## **Timeframes for Patient Safety Incident Investigation (PSII)**

## Where a PSII has been declared the investigation should take no longer than 60 working days.

## Any extension to an investigation should be agreed with the Integrated Quality Governance Team and with the effected parties.

## **Timescales for non PSII incident responses**

## NHS England makes recommendations for timescales which Spire Healthcare will follow.

## These are:

* Swarm huddle - as near to the time the incident occurs as possible but, as a maximum, within 24hrs of it occurring.
* After Action Reviews – within 5 working days of the incident being declared an AAR.
* KSI/Round Table – within 10 working days of the incident occurring (upload documents to datix within 20 working days).

## **Safety action development and monitoring improvement**

## Fully informed and engaged action plans will be crucial to all our incident responses and are included on all enhanced investigation templates. This is vital when trying to reduce the risk of recurrence and making meaningful improvements.

## A Safety Action is an action taken to reduce the risk of harm happening again and improve the level of safety for patients, colleagues and consultant partners within healthcare.

## All actions will be documented in Datix and monitored as part of the quality review.

## Spire Healthcare Hospitals will use the NHS England ‘Safety Action Development Guide’ to support their safety action plans. This can be found at [NHSE Safety Action Development Guide 2022](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf)

## **Safety improvement plans**

## Our Patient Safety Incident Response Plan outlines Spire Healthcare’s Group Priorities for the next 12 months. These priorities were developed following an extensive review of multiple data sets and “soft” intelligence gathered from our colleagues. These priorities offer areas of learning and improvement and have been agreed would benefit from a PSII investigation. After 12 months the expectation is that the frequency of these incidents would have decreased due to effective incident responses and action plans.

## Our learning from incident responses undertaken using the PSIRF will be used to form effective safety improvement plans which will be linked to the organisation's quality improvement activities.

## All data will be used to produce a safety improvement plan which will be driven to inform our QI priorities on an annual basis.

## Monitoring of the progress of safety improvement plans will be performed by National Integrated Quality Governance Team.

# MORTALITY REVIEW PROCESS

## The PSIRF covers all patient safety incidents including expected and unexpected deaths. A Mortality Reporting Process Flowchart and guidance to support hospitals in respect of action required following a patient death (Medical / Surgical / Oncology) can be found inAppendix 19.

* + **Expected / Unexpected Death (CQC - Regulation 16: Notification of death of service user).**
  + An ‘Expected Death’ is defined as a death, that was the expected outcome of an illness or physical condition.
  + An ‘Unexpected Death’ is defined as any death that is not an Expected Death.

For example:

* + - * A death not anticipated during the treatment, intervention, or pathway the patient was admitted for,
      * A death of any patient that is not related to the natural course of their illness,
      * A death of a full-term and viable foetus, or neonate, where there was no underlying pathology,
      * A death of any other person arising out of or in connection with Spire Healthcare activities; where there was a similar unexpected collapse or incident leading to or precipitating the events which led to the death.

## **Case Review (Mortality)**

## A structured review of a case record/note, carried out by the hospital clinical team, to determine whether there were any safety issues, learning and improvement opportunities in the care provided to a patient. Case record review will be undertaken to learn and improve in the absence of any particular concerns about care. This is because it can help find problems where there is no initial suggestion anything has gone wrong. It can also be done where concerns exist, such as when bereaved families or colleagues raise concerns about care.

## **Independent Mortality Advisor Review**

## An independent review of care to identify any concerns within the delivery of care using a Structured Judgement Review methodology (Royal college of Physicians) to assess & identify whether there were any factors in relation to avoidability of the death and also provide an overall care score. See Appendix 19 regarding timeframes for submitting documentation to the Independent Mortality Advisor.

## **Oncology Specialist Review**

## A review of the treatment provided to a patient accessing oncology care (whose death is within 30 days of SACT or Haematology treatment) performed by a nominated cancer specialist clinician from within the Spire Healthcare group. A Structured Judgement Review methodology will be used to identify whether the plan of care and management of the patient was appropriate to the diagnosis / prognosis of the patient and to identify whether there were any factors in relation to avoidability of the death providing an overall care score.

## **Group Mortality Review Committee**

## The Associate Medical Director undertakes a Structured Judgement Review of all deaths within 30 days of surgery (and others where issues were identified) using the Case Review, IMA review and health records. This review is presented to the Group Mortality Review Committee.

## The committee carries out a systematic exercise to review a series of individual case records using a structured methodology to identify any problems in care and to draw learning or conclusions to inform any further action that is needed to improve care within a setting or for a particular group of patients. This is performed on a quarterly basis; the committee agrees the avoidability and overall care score.

## In addition, all oncology mortality reviews will be discussed at the Group Mortality Committee.

## Following this a thematic review of patient deaths to promote learnings / actions group wide, with a particular focus on all deaths within 31 days of surgery/treatment/medical care is undertaken. The Committee reports into Safety Quality & Risk Committee.

## 

## **Avoidability Scores**

## Definitely avoidable

## Strong evidence of avoidability

## Probably avoidable (more than 50:50)

## Possibly avoidable but not very likely (less than 50:50)

## Slight evidence of avoidability

## Definitely not avoidable

## **Overall Care Scores**

## Very Poor Care

## Poor Care

## Adequate Care

## Good Care

## Very Good Care

* **Deaths clinically assessed as more likely than not due to problems in care.**

## Spire Healthcare will further investigate deaths which are concluded with an avoidabililty score of 3 or less and/or an overall care Score of 2 or less during the mortality review process.

## These incidents meet the ‘Learning from Deaths’ criteria; that is, deaths clinically assessed as more likely than not due to problems in care and within PSIRF also meet the criteria listed in the PSIRF plan for a PSII.

## The level of harm for deaths concluded with an avoidabililty score of 3 or less should be recorded as Fatal.

* **External reporting of deaths** 
  + **CQC/HIS/HIW –** notification of a person who has died during an activity provided by Spire Healthcare; or where the person’s death may have been a result of the activity or how it was provided.
  + **Private Healthcare Information Network (PHIN)** – To ensure transparency, hospitals are required to provide PHIN with data about incidents in their care. From February 2024 this will include mortality split by ‘expected’ or ‘unexpected’.

# OVERSIGHT ROLES AND RESPONSIBILITIES

## Spire Healthcare have followed the NHS England Oversight mindset principles which will underpin the oversight of patient safety incident responses:

# Improvement is the focus of PSIRF.

## Oversight should focus on enabling and monitoring improvement in the safety of care, not simply monitoring incident response quality.

# Blame restricts insight.

## Oversight should ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.

## **Learning from patient safety incidents is a proactive step towards improvement.**

## Responding to a patient safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.

## **Collaboration is key.**

## A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.

## **Psychological safety allows learning to occur.**

## Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions.

## **Curiosity is powerful.**

## Leaders have a unique opportunity to do more than measure and monitor. They can and should use their position of power to influence improvement through curiosity. A valuable characteristic for oversight is asking questions to understand rather than to judge.

## **Internal Oversight**

## The Group Medical Director will serve as overall Oversight Lead for the organisation.

## Spire Healthcare has developed a National Meeting and Assurance structure including a ‘Ward to Board Levels of Assurance’ model which will be used to monitor and provide assurance of improvements made in response to patient safety incidents at both hospital and group level. Please see CLIN 01

## **Spire Healthcare Ward to Board Assurance Model.**

## **External Oversight**

## The Hertfordshire and West Essex Integrated Care Board (ICB) an NHS organisation involved in the purchasing of healthcare from the Independent Sector and NHS Trusts for a local population, in agreement with NHS England, has provided support (and will continue to do so) with the Spire Healthcare PSIRF Plan.

## For Hospital sites, the Directors of Clinical Services and Hospital Directors, will ensure that they have a relationship with their local ICB equivalents so that they participate in sharing of learning across the wider healthcare network as specified within PSIRF. This policy will be updated as this process becomes clearer during the transition.

## NHSE have indicated that they are working with the Care Quality Commission (the government body who regulates, monitors, and inspects healthcare in England) to provide guidance to healthcare providers on how their inspections will change with the implementation of PSIRF. Again, this policy will be updated once that guidance has been received.

## Our PSIRF plan and policy has been designed to ensure that we fulfil our requirements to Health Inspectorate Wales (HIW) and Health Improvement Scotland (HIS). The organisation has participated in meetings with IHPN and both regulators and governments who have been supportive with our PSIRF arrangements.

# COMPLAINTS AND APPEALS

## Spire Healthcare’s Complaints Management Policy (HOP02) is separate from PSIRF and outlines the process for both private patients overseen by the Independent Sector Complaints Adjudications Service (ISCAS) and NHS patients overseen by the Parliamentary and Health Service Ombudsman. It is hoped that patients and their families will not feel the need to complain about how a patient safety incident, in which they were involved, is managed because colleagues at the site will have offered them the opportunity to be involved in the learning response. However, colleagues must still provide patients with a copy of the ‘Your Opinion Matters’ Leaflet which details the way patients can provide feedback to Spire Healthcare and how they can expect any concerns or complaints to be managed.

## The leaflet details the four-stage process for England, Scotland, and Wales, which includes how patients/their families can appeal which includes locally (at the hospital the incident occurred), organisationally (Spire Healthcare Central Customer relations Manager) or externally (by an Independent Adjudicator).

# REFERENCES

## Learn from patient safety events (LFPSE) service. Available at: [NHS England » Learn from patient safety events (LFPSE) service](https://www.england.nhs.uk/patient-safety/patient-safety-insight/learning-from-patient-safety-events/learn-from-patient-safety-events-service/) [accessed 14.3.2024]

## NHSE Patient Safety Incident Response Framework (2022). Available at: [NHSE PSIRF 2022](https://www.england.nhs.uk/patient-safety/incident-response-framework/)

## NHSE and the Healthcare safety Investigation Branch (2022) Engaging and involving patients, families and staff following a patient safety incident. Available at: NHSE [HSIB 2022 Engaging and involving patients, families and staff following a PSI](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-2.-Engaging-and-involving...-v1-FINAL.pdf)

## NHSE (2022) Guide to responding proportionately to patient safety incidents. Available at: [NHSE Guide to responding proportionately to PSIs 2022](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-3.-Guide-to-responding-proportionately-to-patient-safety-incidents-v1.1.pdf)

## NHSE (2022) patient safety Incident Response Standards. Available at: [NHSE PSIRF Standards 2022](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-5.-Patient-Safety-Incident-Response-standards-v1-FINAL.pdf)

## Oversight roles and responsibilities specification (2022). Available at: [NHSE Oversight roles and responsibilities 2022](https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-4.-Oversight-roles-and-responsibilities-specification-v1-FINAL.pdf)

## Psychological Safety. Available at: [Psychological Safety – Workplace Training, Workshops and Consultancy on Psychological Safety, Just Culture, Resilience and High Performing Teams (psychsafety.co.uk)](https://psychsafety.co.uk/) [accessed 21.2.2024]

## RCP Using the structured judgement review method. Available at: <https://www.rcplondon.ac.uk/sites/default/files/media/Documents/NMCRR%20guide%20England_0.pdf>

# ASSOCIATED POLICIES

|  |  |
| --- | --- |
| CLINI 01 | Spire Healthcare Standards for Hospital Governance |
| CLINI 09 | Prevention and management of pressure ulcers |
| CLINI 29 | SSD Vigilance Policy |
| CLINI 45 | Reducing the risk of DVT and PE (VTE) in patients admitted to hospital |
| CLINI 52 | Management of Blood Transfusion Policy |
| CLINI 57 | End of Life Policy |
| CLINI 59 | Safe Standards in the Perioperative Environment |
| CLINI 64 | Prevention and Management of Falls |
| CLINI 83 | Surveillance for HCAI Policy |
| FIN 03 | Risk Management Policy |
| FIN 05 | Duty of Candour |
| FIN 14 | Management of Claims |
| HOP 02 | Complaints Policy |
| HS 09 | Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR) |
| Med 01 SOP 05 | Managing Performance Concerns |
| MED 02 | Consultants’ Handbook |

# GLOSSARY OF TERMS:

**After Action Review (AAR)** A structured approach for reflecting on the work of a group and identifying strengths, weaknesses, and areas for improvement.

**Candour**  The quality of being open and honest.

**Duty of Candour** Responsibility to be open and transparent in relation to a safety incident

**Integrated Care Boards (ICBs)** A statutory NHS organisation which is responsible for developing a plan for meeting the health needs of the population, managing the NHS budget, and arranging for the provision of health services in a geographical area. Formerly known as a CCG.

**Just Culture**  A culture that balances fairness, learning and accountability.

**Learning from Patient Safety Events** National NHS service for the recording and analysis of patient safety events that occur in healthcare.

**Learning Response** Any response to a patient Safety incident that incorporates a system-based approach to capturing learning to inform safety actions for improvement. The system here is the ‘Work System’ (see below).

**Patient Safety Incident (PSI)** Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm.

**Patient Safety Incident Investigation (PSII)** A PSII is undertaken when an adverse event or near-miss indicates significant patient safety risks and the potential for new learning.

**Psychological Safety** An environment characterised by openness and trust that allows team members to feel comfortable taking risks and making mistakes.

**Safety Actions** Actions to reduce risk following the identification and agreement of the aspects of a work system (see below) where change could reduce risk and the potential for harm.

**Swarm Huddle** A quick analysis occurring immediately (or within 24 hrs) of an incident to understand what happened, how it happened and what needs to be done to reduce the risk of it happening again. Includes all those involved in the incident ‘swarming’ together.

# APPENDICES

# Appendix 1 - PSIRF Plan

# APPENDIX 2 - PSIR Template

# Appendix 3 - PSII TEMPLATE

# Appendix 4 - PSII TEMPLATE INC GUIDANCE

# Appendix 5 - PSII TOR

# Appendix 6 - AFTER ACTION REVIEW TEMPLATE

# Appendix 7 - ROUND TABLE REVIEW TEMPLATE

# Appendix 8 - ROUND TABLE REVIEW GUIDANCE

# Appendix 9 - SWARM HUDDLE TEMPLATE

# Appendix 10 - KSI REVIEW MEETING TOR

# Appendix 11 - KSI REVIEW MEETING TEMPLATE

# Appendix 12 - KSI Process CQC Letter October 2023

# Appendix 13 - KSI REVIEW GUIDANCE

# Appendix 14 - BLOOD TRANSFUSION AND LABORATORY MEDICINE INCIDENT INVESTIGATION

# APPENDIX 15 - VTE Case Review

# APPENDIX 16 - Pressure Ulcer Case Review

# APPENDIX 17 - SSI Case Review

# APPENDIX 18 - PATIENT SAFETY INCIDENT RESPONSE FLOWCHART

# APPENDIX 19 - MORTALITY FLOWCHART

# APPENDIX 20 - MORTALITY CASE REVIEW

# APPENDIX 21 - MORTALITY review – sact

# APPENDIX 22 - MORTALITY review IMA

# APPENDIX 23 - MORTALITY STRUCTURED JUDGEMENT REVIEW

# APPENDIX 24 - Condolence Letter Template

# APPENDIX 25 - medical examiner process

# APPENDIX 26 - LEVELS OF HARM – CLINICAL

# APPENDIX 27 - Spire Healthcare just culture: Managers step by step guide

# APPENDIX 28 - PSIR guidance

# Appendix 29 – Investigation of Wrong Site Imaging

# Appendix 30 - INVESTIGATION OF DOSE GREATER THAN INTENDED

Please complete the quality assessment below.

**Quality Assessment**

|  |  |
| --- | --- |
| Reference: | Clini 103 |
| Policy name: | PSIRF Policy |
| Name of the person completing: | Matthew Minter |
| Who has been consulted on this policy: | All stakeholders overseen by PSIRF Programme Board |
| Director owning the policy (job title): | Spire Healthcare Group Director of Integrated Quality Governance |
| Directors name: | Maryellen Dean |

Has the executive responsible for this policy seen and approved this policy? Yes  No

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Director | Dr Cathy Cale | Date | 22/01/2023 |

Which stakeholders have been involved in the development / review of this policy?

|  |  |
| --- | --- |
| Please detail | Group Medical Director, Director of Integrated Quality Governance, Governance Leads and Lead ICB |

How will compliance with this policy be monitored / audited?

|  |  |
| --- | --- |
| Please detail | Patient Safety Incident Review Working Group (PSIRG) oversight  Compliance with MED06 – Managing Consultant Performance Concerns process  Reporting of incidents to Operational SQ&R, SQ&R and CG&S Committees |

Is training required to implement this policy? Yes  No

|  |  |
| --- | --- |
| Please detail | Ongoing drop in PSIRF related sessions, induction for new starters |

Is there a cost implication in the implementing of this policy? Yes  No

If there is a cost implication has this been agreed? Yes  No

|  |  |
| --- | --- |
| Please detail | N/A |

Is there a resource implication in the implementation of this policy? Yes  No

|  |  |
| --- | --- |
| Please detail | N/A |

Please complete the equality assessment below.

**Equality Assessment**

***Positive impact:*** *a policy / document where the impact on a particular group of colleagues / patients is more positive than for other colleagues. It can also include legally permitted positive action initiatives designed to remedy workforce imbalance, such as job interview guarantee schemes for disabled people.*

***Negative impact****: a policy / document where the impact on a particular group of colleagues / patients is more negative than for other colleagues (e.g., where the choice of venue for a colleague social occasion precludes members of a particular faith or belief group from participating).*

***Neutral impact:*** *a policy / document with**neither a positive / negative impact on any group or groups of colleagues / patients, compared to others.*

|  |  |  |
| --- | --- | --- |
| **Group: Colleague / Patient** | **Considerations (examples)** | **Impact (check box)** |
| Sex |  | Positive  Neutral  Negative |
| Pregnancy / maternity |  | Positive  Neutral  Negative |
| Disability | *Do we need to consider large print or adapt for colleagues with Dyslexia?* | Positive  Neutral  Negative |
| Race (inc. ethnicity /nationality) | *Is the policy inclusive and take into account different groups of people?* | Positive  Neutral  Negative |
| Age | *Are their ways older / younger people might find it difficult to engage with the policy?* | Positive  Neutral  Negative |
| Gender reassignment / trans / non-binary | *The language used inclusive of all groups e.g. they instead of he/she.* | Positive  Neutral  Negative |
| Marriage /civil partnership |  | Positive  Neutral  Negative |
| Lesbian / gay / bisexual groups | *Is the language used inclusive of LGBTQ+?* | Positive  Neutral  Negative |
| Faith / belief groups: | *Do faith groups experience a disadvantage in relation to the policy?* | Positive  Neutral  Negative |
| Welsh language | *Level of fluency?* | Positive  Neutral  Negative |
| Social deprivation | *Are their social factors to consider?* | Positive  Neutral  Negative |

If there is a negative impact on any equality target groups, can this impact be legally and objectively justified?

|  |  |
| --- | --- |
| Please detail | No |

Does this policy promote equality? Consider, does the policy eliminate unlawful or unjustifiable discrimination, promote equality of opportunity, promote positive attitudes, eliminate harassment and bullying or victimisation, promotes inclusion and participation and eliminate health inequalities for both colleagues and patients?

|  |  |
| --- | --- |
| Please detail | Yes – See section 5.0 ADDRESSING HEALTH INEQUALITIES |

If there is no evidence that the policy promotes equality, what changes, if any, could be made to achieve this?

|  |  |
| --- | --- |
| Please detail | N/A |

**Author Declaration**

Please confirm you have thoroughly assessed the policy / document against the above criteria

|  |  |
| --- | --- |
| **Signed** | Matthew Minter |

**Policy / Document Guide** (for reference only)

All policies and appendices (new and updated) should be approved at the Policy Approval Committee (PAC). The committee meets each month and final papers should be sent for consideration no later than 10 days prior to the next meeting. For example if the meeting is taking place on the 24th of the month the last date for papers will be the 14th. Dates of meetings and final dates for papers can be found at: <https://intranet.spirehealthcare.net/integrated-quality-governance/policy-management/>

CHECKLIST

Consultation has taken place prior to final papers being submitted. Details of who to consult with can also be found on the above link.

I can confirm that the legal team have been consulted on this policy prior to the final copy being submitted to PAC.

All policies and appendices have been assigned to a relevant committee and executive director and that both have been consulted and are aware of the policy / appendix prior to submission to PAC.

GUIDANCE NOTES

|  |  |
| --- | --- |
| Reference: | CLINI 103 |
| Policy Name: | PSIRF Policy |
| Directorate: | Name of the directorate in which the author sits. |
| Committee: | Name of the committee which has responsibility for this policy area of work |
| Author Name: | Your name (one person only) |
| Author Job Title: | Your job title |
| Issue Date: | March 2024 |
| Next Review Date: | March 207 |
| Issue Number: | 1 |